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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRISBY, KESHA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,016	Applicant(s) FEYGIN ET AL.	
	Examiner KESHA FRISBY	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,13-19,21-25,28 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,13-19,21-25,28 and 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/6/2008 has been entered.

Status of Claims

After the request for continued examination was filed on 3/6/2008, claims 1, 4-7, 13-19, 21-25, 28 & 33-40 are pending in this application. Claims 2, 3, 8-12, 20, 26, 27 & 29-32 were cancelled.

Information Disclosure Statement

2. The information disclosure statement filed 12/4/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Foreign Patent Document does not include a translation. The examiner is unable to determine what the document entails since it is in a foreign language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with

the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 35 & 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenberg (U.S. Patent Number 6,654,000).

Referring to claim 35, Rosenberg discloses a pseudo skin (barrier 22); a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure (mechanical apparatus 25 and trocar 24), including at least one mechanism (mechanical apparatus 25 and trocar 24) for performing a skin-interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said skin and are covered by said pseudo skin (column 5 lines 37-56); and a housing (within the “body” of the patient), wherein said housing contains said plurality of mechanisms (Fig. 1 & column 5 lines 37-56).

Referring to claim 38, Rosenberg discloses wherein at least one of either a needle or catheter is disposed outside of said housing until inserted therein during a simulated vascular-access procedure (Fig. 1 & the associated text).

Referring to claim 39, Rosenberg discloses further comprising a data processing

system, wherein said data processing system receives signals from sensors that are associated with said plurality of mechanisms (column 10 lines 22-24).

Referring to claim 40, Rosenberg discloses wherein said plurality of mechanisms comprise discrete devices, wherein a first of said devices (column 11 line 47- column 12 line 2) is for enabling a user to perform a skin-stretch technique, a second of said devices (trocar 24) is for receiving a needle or catheter or both, and a third of said devices (column 12 lines 46-49) is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4 & 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (U.S. Patent Number 6,654,000) in view of Pugh (U.S. Publication Number 2003/0031993).

Referring to claim 1, Rosenberg discloses pseudo skin (barrier 22); a receiver (trocar 24), wherein said receiver receives an end effector (laparoscopic tool 18) through an insertion region in said pseudo skin (column 5 lines 38-47); and a first device (mechanical apparatus 25) for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein said receiver and

said first device are disposed beneath said pseudo skin and are covered by said pseudo skin (Fig. 1 & column 5 lines 37-56). *Rosenberg does not disclose wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin and further said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.* However, Pugh teaches wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin (Fig. 3 and paragraphs 0041 & 0042) and further said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus (One region would be closer to a user than another region, depending on the location of the user with respect to the apparatus). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include palpation, as disclosed by Pugh, incorporated into Rosenberg in order to check for organs that on the organ surface or on the skin.

Referring to claim 4, Rosenberg, as modified by Pugh, teaches further comprising a second device (paragraph 0012 of Pugh) for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (paragraphs 0012 & 0013 of Pugh).

Referring to claim 5, Rosenberg, as modified by Pugh, teaches wherein: said second skin-interaction technique comprises skin stretching (Figs. 14C, 15 & 16 of Pugh), and said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus (One region would be closer to a user than another region, depending on the location of the user with respect to the apparatus of Pugh).

7. Claim 6, 7 & 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg/Pugh and further in view of Cunningham et al. (U.S. Patent Number 6,470,302).

Referring to claim 6, Rosenberg/Pugh discloses the apparatus of claim 1.

Rosenberg/Pugh does not disclose further comprising a housing, said receiver and said first device are contained within said housing wherein said housing has an anterior portion, a posterior portion, an upper surface and a lower surface wherein, in use: said anterior portion is proximal to a user; said posterior portion is distal to said user; said lower surface is proximal to a support surface on which said apparatus resides; and said upper surface is distal to said support surface. However, Cunningham et al. teaches further comprising a housing (interface device 30), said receiver (shaft 44) and said first device (catheter needle assembly 47) are contained within said housing (interface device 30); said housing has an anterior portion and a posterior portion (Fig. 3); in use, said anterior portion is proximal to a user; and said posterior portion is distal to said user (Fig. 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include housing, as disclosed by Cunningham et al.,

incorporated into Rosenberg/Pugh in order to protect the receiver and first device from getting damaged.

Referring to claim 7, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein the upper surface is no more than about 5 inches above the lower surface, the housing units 33 and 40 in Fig. 4 appear to have only a slightly bigger height than the mouse 44. Since a mouse is generally about 1.5 inches high, one could assume that housings 33 and 40 in Fig. 4 are probably about 2 or 3 inches high. Additionally, Pugh discloses that the size of the anatomical simulator and organs represent expected ranges of human size, shape, and other qualities (Paragraph [0038]). Therefore, if the invention were being used to simulate the anatomy of a baby or small child, the height of the anatomical simulator would be less than about 5 inches.

Referring to claim 13, Rosenberg/Pugh, as modified by Cunningham et al., discloses further comprising a second device (paragraph 0012 of Pugh) for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (paragraphs 0012 & 0013 of Pugh).

Referring to claim 14, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein: said second skin-interaction technique comprises skin stretch (Figs. 14C, 15 & 16 of Pugh).

Referring to claim 15, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first device (paragraph 0012 of Pugh).

Referring to claim 16, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first end of said receiver (Items 16 & 20 in Fig. 1, paragraph 0037, items 26, 28, 29 & 30 in Fig. 3 & paragraphs 0041 & 0042 of Pugh).

Referring to claim 17, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said first end of said receiver is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim 18, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein an upper-most surface of said first device extends a greater distance above a lowermost surface of said housing than said first end of said receiver (Fig. 2 of Pugh).

Referring to claim 19, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein an upper-most surface of said first device extends further above a lowermost surface of said housing than an upper-most surface of said second device (Fig. 8 of Pugh).

Referring to claim 21, Rosenberg/Pugh, as modified by Cunningham et al., discloses further comprising an electronics/communications interface, wherein: said electronics/communications interface receives signals from sensors that are associated with at least one of said first device or said receiver (paragraphs 0014-0017 of Pugh); and said electronics/communications interface is disposed beneath said pseudo skin and covered by said pseudo skin (wires located inside simulator of Pugh).

Referring to claim 22, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface is closer to said posterior portion of

Art Unit: 3714

said housing than said first device (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 23, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface is closer to said posterior portion of said housing than said receiver (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 24, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface comprises a printed circuit board, and further wherein a major surface of said printed circuit board is disposed orthogonal to an uppermost surface of said first device (paragraph 0045 & Item 33 in Fig. 4 of Pugh).

8. Claims 25, 28 & 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Cunningham et al..

Referring to claim 25, Rosenberg discloses a housing (within the “body” of the patient); an end effector (laparoscopic tool 18), wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure (Fig. 1 & the associated text); and a plurality of mechanisms (mechanical apparatus 25 and trocar 24), wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin (Fig. 1 & column 5 lines 37-56), and wherein said plurality of mechanisms include: (a) a first mechanism (mechanical apparatus 25) is for simulating skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on

said pseudo skin; and (b) a second mechanism (trocar 24) for receiving said end effector. *Rosenberg does not disclose housing, wherein said housing has an opening in an uppermost surface thereof; pseudo skin, wherein said pseudo skin covers said opening.* However, Cunningham et al. teaches housing, wherein said housing has an opening in an uppermost surface thereof (Fig. 3); pseudo skin, wherein said pseudo skin covers said opening (Fig. 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include housing, as disclosed by Cunningham et al., incorporated into Rosenberg in order to protect the receiver and first device from getting damaged.

Referring to claim 28, Rosenberg, as modified by Cunningham et al., discloses wherein said mechanisms includes a third mechanism (column 11 line 47 – column 12 line 2) for simulating at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effector is at least one of either a needle or a catheter (column 6 lines 4-13).

Referring to claim 33, Rosenberg, as modified by Cunningham et al. teaches wherein said housing has an anterior end and a posterior end (Fig. 3 of Cunningham et al.), wherein in use, said anterior end is proximal to a user; and wherein a portion of said second mechanism is flanked by said first mechanism proximal to said anterior end and said third mechanism proximal to said posterior end (Fig. 3 of Cunningham et al.).

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg/Cunningham et al. and further in view of Pugh.

Art Unit: 3714

Referring to claim 34, Rosenberg/Cunningham et al. discloses the apparatus of claim 28. *Rosenberg/Cunningham et al. does not disclose wherein a user interacts with the first mechanism at a first site on said pseudo skin, and wherein the user interacts with the second mechanism at a second site on said pseudo skin, and wherein the user interacts with the third mechanism at a third site on said pseudo skin.* However, Pugh teaches wherein a user interacts with the first mechanism at a first site on said pseudo skin, and wherein the user interacts with the second mechanism at a second site on said pseudo skin, and wherein the user interacts with the third mechanism at a third site on said pseudo skin; and locations of each of said first site, second site, and third site on said pseudo skin corresponds to locations of said first mechanism, second mechanism, and third mechanism, respectively within said housing, Pugh discloses that a user may interact with a plurality of simulated organs (i.e., mechanisms) via a plurality of openings on the simulator (Figs. 14A-C, 15, and 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include user interaction, as disclosed by Pugh, incorporated in to Rosenberg/Cunningham et al. in order to perform medical exams with direct manual contact with a body or organ surface.

10. Claims 36 & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg.

Referring to claims 36 & 37, Rosenberg et al. discloses the apparatus of claim 35.

Rosenberg does not disclose expressly that the housing is no more than about 4 or 5 inches in height. Instead, Rosenberg indicates using a housing (column 5 lines 54-56).

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to have the housing having any measurements because Applicant has not disclosed that having adaptive architecture on a second computer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Rosenberg's system, and applicant's invention, to perform equally well with the housing taught by Rosenberg or the claimed housing is no more than about 4 or 5 inches in height because both housings would perform the same function of contain the mechanism.

Therefore, it would have been prima facie obvious to modify Rosenberg to obtain the invention as specified in claims 36 & 37 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rosenberg.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 4-7, 13-19, 21-25, 28 & 33-40 have been considered but are moot in view of the new ground(s) of rejection and applicant's arguments filed 3/6/2008 have been fully considered but they are not persuasive.

Art Unit: 3714

On page 10, the applicant asserts in claim 4 that Rosenberg does not disclose “a second device for performing a second skin-interaction technique on the pseudo skin” is disposed beneath and covered by pseudo skin. The examiner agrees with applicant because the examiner has used Pugh to teach this limitation and has cited the citations from the Pugh reference. See the above rejection. In addition, for this limitation, features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. Also, a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Regarding claim 5, the applicant asserts that Rosenberg does not disclose a second skin-interaction technique. This is assertion is true because the examiner looks to Pugh to teach a second skin-interaction technique. Please see the above rejection.

Regarding claims 25 & 35 on pages 11 & 12, the applicant asserts that Rosenberg does not disclose “a plurality of mechanism ... contained completely within the housing and a first mechanism for simulating a skin-stretch technique” and “a plurality of mechanisms with which a user interacts for simulation of a vascular-access procedure, including at least one mechanism for performing a skin-interaction technique that is performed on the pseudo skin”, respectively. However, the examiner disagrees. Please see the rejection above. In addition, for this limitation, features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished

from the prior art in terms of structure rather than function. Also, a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

On pages 12 & 13, the applicant asserts that there is no disclosure in either Rosenberg or Pugh of a "first device for performing a first skin-interaction technique that is used in conjunction with a vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin."

However, the examiner disagrees. Rosenberg discloses "first device for performing a first skin-interaction technique that is used in conjunction with a vascular-access procedure (mechanical apparatus 25)." In addition, for this limitation, features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. Also, a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Further, Pugh teaches "wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin" (Fig. 3 & paragraphs 0041 & 0042). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the

Art Unit: 3714

features upon which applicant relies (i.e., the techniques are different than the palpation techniques that are used “in conjunction with a simulated vascular-access procedure, “such as to palpate for hidden veins or to determine if a vein is sufficiently straight for catheterization.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KESHA FRISBY whose telephone number is (571)272-8774. The examiner can normally be reached on Monday-Friday 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3714

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. F./
Examiner, Art Unit 3714

/Ronald Laneau/
Supervisory Patent Examiner, Art Unit 3714
03/25/08